



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 26 2005

Food and Drug Administration  
Rockville MD 20857

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Frederick S. Mayer, R. Ph., M.P.H.  
President/CEO  
Pharmacists Planning Services, Inc.  
101 Lucas Valley Road, Suite 210  
San Rafael, CA 94903

Re: Docket No. 2000P-1671/CP1

Dear Mr. Mayer:

This letter responds to the citizen petition submitted by Pharmacists Planning Services, Inc., requesting that the Food and Drug Administration (FDA) issue a patient medication guide (MedGuide) for distribution with all prescription non-steroidal anti-inflammatory drugs (NSAIDs), including the so-called "COX-2 selective" drugs, to provide patients appropriate warning and risk information relating to gastrointestinal (GI) bleeding associated with the use of these drugs. For the reasons described below, your petition is granted.

On April 7, 2005, FDA issued a Public Health Advisory (PHA) in which it announced several actions relating to both COX-2 selective and non-selective NSAIDs, including plans to issue a MedGuide for patients addressing the cardiovascular and GI risks associated with the use of prescription drugs in this class. The MedGuide will inform patients of the need to discuss with their doctor the risks and benefits of using prescription NSAIDs, and the importance of using the lowest effective dose for the shortest duration possible if treatment with an NSAID is warranted for an individual patient.

We have attached the PHA and related documents issued by FDA on April 7, and our memorandum entitled "Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk." These documents detail the scientific and regulatory findings upon which FDA based these actions.

Accordingly, your petition is granted. Thank you for your continuing interest in promoting public awareness of safe use of medications.

Sincerely,

Steven K. Galson, M.D., M.P.H.  
Acting Director  
Center for Drug Evaluation and Research

Attachments

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